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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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March 9, 2001

Dr. David Campagna
ATSDR
Division of Health Studies
Health Investigations Branch
Executive Park, Building 4
1600 Clifton Road, NE, E-31
Atlanta, GA 30333

RE: Vasquez Boulevard/ Interstate 70 NPL Site, Proposed Soil Pica, Soil Ingestion and Health Outcome Investigation

Dear Dr. Campagna:

Thank you for providing EPA the opportunity to review ATSDR's draft proposal for a Soil Pica, Soil Ingestion, and Health Outcome Investigation at the Vasquez Boulevard/Interstate 70 (VB/I70) Site. EPA's VB/I70 team sincerely appreciates your willingness to come to Denver on numerous occasions to explain the draft proposal and to seek our input. I am writing to provide you with our comments on the draft proposal and suggestions for making the investigation more useful in supporting both public health and remedial decisions at the Site.

The following comments are based on our understanding that there is general agreement between ATSDR and EPA on two key points related to the proposed investigation:

A. There is currently insufficient data to allow reliable estimates of the risk of acute effects associated with exposure to arsenic by children who exhibit soil pica behavior.

B. Until acute risks can be estimated with more certainty, public health actions are appropriate responses in areas where soil pica behavior is suspected.

We believe that the general objectives of ATSDR's proposed investigation, stated on page 4 of the draft proposal, need to be more specific to the information needs at the VB/I70 site in order for the investigation to be useful to both EPA and ATSDR in developing and implementing an effective risk management strategy to address the potential acute arsenic risk associated with soil pica behavior. We are concerned that meeting ATSDR's proposed general objectives is not likely to result in a better understanding of the nature and frequency of soil pica behavior nor better estimates of exposure in a soil pica scenario, two issues which EPA and ATSDR agree are important to address.

We offer the following comments on the objectives to guide the investigation to collect more meaningful information for the VB/I70 Site. Please consider modifying the objectives and investigation design to address these comments.

1. Risk assessment calculations indicate that there are two types of exposure which are of concern within the residential areas of the VB/I70 Site: (1)chronic exposure of residents to lead and arsenic in soil; and (2) acute exposure of children to arsenic in soil. It is not clear whether the proposed investigation is focused on gathering information on one or both of these exposures. It is important that ATSDR clarify this because the populations of concern, the levels of contaminants in soil which may be of concern, the behaviors associated with exposure, and the health effects of concern are very different for the two types of exposure. EPA suggests that if available resources are limited, it will be most useful to focus on the acute arsenic exposure since engineering remedial actions will address risks associated with chronic exposure.

2. If the proposed investigation is intended to focus on gathering information specific to **acute exposure to arsenic**, the overall general objective of the investigation should be to :

> Collect sufficient information to (a) allow reliable risk estimates of acute arsenic exposure in a soil pica exposure scenario at the VB/I70 Site and (b) assess the health impacts of soil pica behavior on the population of children in the VB/I70 community.

Detailed study plans should be developed using the data quality objectives process. The plans should describe how specific information will be collected and used to meet the overall general objective. The information needs are to :

- Establish the mass distribution (in milligrams ingested per event) and the frequency distribution (in number of events) of soil intake rates for a sufficient number of children over a sufficient number of days to allow the soil intake rate associated with soil pica behavior and the frequency of its occurrence to be determined with an acceptable level of confidence.

- Determine the relative bioavailability of arsenic in soil when ingested in amounts typical of soil pica behavior

- Determine the level of recent arsenic exposure in children attributable to arsenic in soil by collecting urine and possibly hair samples

- Identify clinical signs of health effects associated with arsenic exposure. Determine whether there is a correlation between observed health effects, soil intake, and absorbed arsenic dose.

- Identify instances of suspected acute arsenic poisoning. Refer such cases for further medical evaluation and health education.

3. If the proposed investigation is intended to focus on gathering information specific to **chronic exposure to arsenic and lead**, the overall general objective of the investigation should be to :

> Collect sufficient information to assess the level of recent exposure to lead and arsenic in the population in the VB/170 study area and to guide public health responses where appropriate.

Detailed study plans should be developed using the data quality objectives process. The plans should describe how specific information will be collected and used to meet the overall general objective. The information needs are to :

- Determine the level of recent arsenic and lead exposure in the population residing in the VB/170 study area by collecting urine, hair, and blood samples

- Identify instances of confirmed unacceptable levels of exposure to arsenic or lead. Refer such cases for further medical evaluation and health education. Determine whether the exposure is attributable to arsenic or lead in soil.

4. EPA also has a number of general comments which apply to the detailed study plans which presumably will be developed by ATSDR. Please consider the following when you develop these plans:

A. A sufficient number of participants and a sufficient study duration will be required for the investigation to have acceptable power. There is no evidence in the proposal that consideration has been given to the questions of power, confidence, and participation rates.

B. Each study plan should include decision rules which will be used to make decisions with the information collected. As an example, a decision rule for the determination of soil pica frequency may be:

> *If the number of participants is _____ (determined by ATSDR) and the observed frequency of soil pica behavior is 1% of the participants, 1 event in 1 year of observation, then conclude that the frequency of pica behavior is not likely to be greater than 1% exhibit the behavior more than once. If soil pica behavior is not observed, then conclude it is not likely to occur in the VB/170 population. The probability of a false negative (concluding that pica does not occur when it actually does) will be kept to (determined by ATSDR) ___%.*

Similar decision rules should be developed for each study, including decision rules for when medical referrals and health education will be required.

C. If ATSDR decides to investigate lead exposure in the VB/I70 study area, the targeted population should be those who reside on property with elevated lead in soil. These are not in all cases the same properties as those with elevated arsenic levels. The draft investigation proposal does not make this important distinction. The VB/I70 data indicates that the majority of properties with the highest concentrations of lead have relatively low concentrations of arsenic.

5. The background information in the draft investigation proposal should be updated with the most recent VB/I70 Site information. The following comments provide suggested changes:

A. Add to the first paragraph in the background section: Phase I and Phase II sampling programs were screening level evaluations to support EPA decisions about whether to undertake time critical removal actions using Superfund authority.

B. Please summarize the findings of the medical monitoring program overseen by the Colorado Department of Public Health and Environment in Globeville.

C. Add to the third paragraph in the background section: In July, 1999, EPA listed the VB/I70 Site on the National Priorities List. In August, 1999, EPA implemented a large soil sampling program known as "Phase III" as part of its remedial investigation of the Site. The sampling program was designed to support a baseline risk assessment.

D. Please correct the statements about the preliminary results of Phase III. 33 properties had average soil arsenic concentrations of 400 mg/kg or greater, not 23 as stated in the proposal. No properties had average soil lead concentrations greater than 2000 mg/kg, not 2 as stated in the proposal. All of these properties have been cleaned up by EPA.

E. The proposal sates that "In some areas, arsenic soil levels exceeded 1000 mg/kg." Please include the fact that EPA's removal actions have cleaned up these areas and that 2990 properties were sampled in Phase III.

As we discussed previously, EPA may be able to contribute resources to aspects of the proposed investigation that address information needs common to developing a remedial action strategy and a public health action plan for the Site. We look forward to working with you in the development of the final plan for the investigation.

Sincerely,

Bonnie Lavelle
Remedial Project Manager

cc: VB/I70 Working Group